

Message Text

UNCLASSIFIED

PAGE 01 STATE 184440

44

ORIGIN OES-05

INFO OCT-01 ARA-10 ISO-00 HEW-06 /022 R

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----- 086904

P 051808Z AUG 75
FM SECSTATE WASHDC
TO AMEMBASSY PANAMA PRIORITY

UNCLAS STATE 184440

E.O. 11652: N/A

TAGS: ,BIO, PN

SUBJECT: DEXTROSE SOLUTION IN POLYETHYLENE BAGS

REF: PANAMA 4609

FDA ADVISES THAT DEXTROSE OR ANY OTHER LARGE-VOLUME
PARENTERAL PACKAGED IN POLYETHYLENE(WHERE THE SOLUTION
IS IN DIRECT CONTACT WITH THE POLYETHYLENE) WOULD BE
CONSIDERED A "NEW DRUG". THIS DRUG WOULD REQUIRE A
"NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION FOR A NEW
DRUG" AND/OR A "NEW DRUG APPLICATION" UNDER SECTION 505
OF FEDERAL FOOD, DRUG, AND COSMETIC ACT. IT WOULD ALSO
BE SUBJECT TO ALL REGULATIONS PERTAINING TO "IND'S" AND
"NDA'S" IN CODE OF FEDERAL REGULATIONS, TITLE 21. KISSINGER

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NNN

Message Attributes

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Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
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Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
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Margaret P. Grafeld
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To: PANAMA
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